



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2022-0070]

Draft Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on the *Draft Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns* (2022 Draft Guidelines). The 2022 Draft Guidelines provide updates to the 2013 publication, *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from the CDC and the Council of State and Territorial Epidemiologists (CSTE)* (2013 Guidelines). The updates provide state, tribal, local, and territorial health departments guidance for a revised and expanded approach to evaluating concerns about unusual patterns of cancer in communities, including those associated with local environmental concerns. The 2022 Draft Guidelines provide recommendations only; compliance with these recommendations is voluntary.

DATES: Written comments must be received on or before
**[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE
FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket
No. CDC-2022-0070, by either of the methods listed below.

- *Federal eRulemaking Portal:*
<http://www.regulations.gov>. Follow the instructions
for submitting comments.
- *Mail:* Division of Environmental Health Science and
Practice, National Center for Environmental Health,
Centers for Disease Control and Prevention, Attn:
Docket No. CDC-2022-0070, 4770 Buford Highway NE,
Mailstop S-106-6, Atlanta, GA 30341.

Instructions: All submissions received must include the
agency name and docket number. All relevant comments,
including any personal information provided will be posted
without change to <http://regulations.gov>. Do not submit
comments by email. CDC does not accept comments by email.
For access to the docket to read background documents or
comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Alisha Etheredge, Centers
for Disease Control and Prevention, National Center for
Environmental Health, Division of Environmental Health
Science and Practice, 4770 Buford Highway NE, Mailstop S-
106-6, Atlanta, GA 30341; Telephone: 770-488-4024; Email:
CCGuidelines@cdc.gov.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data related to the 2022 Draft Guidelines. In addition, CDC invites comments specifically on the following:

1. Please comment on the strengths and limitations of the enhanced approach for routine, proactive evaluation of cancer patterns.
2. Please comment on the strengths and limitations of the recommendations for enhancing communications and engagement with communities.
3. Please comment on the strengths and limitations of the enhanced phased approach for responding to community inquiries.
4. Please comment on the strengths and limitations of the new criteria for suggesting continued assessment of a report of an unusual pattern of cancer and addressing environmental concerns.
5. Please comment on the strengths and limitations of the revised definition of a cancer cluster.
6. Please comment on the strengths of the 2022 Draft Guidelines and provide suggestions to address weaknesses.
7. Please comment on whether the language in the 2022

Draft Guidelines is sufficiently clear for both the general public and state, tribal, local, and territorial public health agency staff, in terms of comprehension of the investigative process and recommendations.

8. Please provide any additional comments about the document.

CDC will carefully consider all comments submitted in preparation of the final *Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns* and may revise the final document as appropriate.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure.

Comments will be posted on <https://www.regulations.gov>.

Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact or withhold submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate or near duplicate examples of a mass-mail campaign. **Do not submit comments by**

email. CDC does not accept comment by email.

Background

CDC/ATSDR develops guidance for state, tribal, local, and territorial (STLT) public health departments on how to respond to cancer cluster concerns. The current 2013 Guidelines provide a rationale and tool to assist STLT public health agencies in applying a systematic approach when responding to inquiries about suspected unusual patterns of cancer in residential or community settings. Since publication of the 2013 Guidelines, there have been technical and scientific advancements in areas such as data availability and analytic and geospatial methods.

In the 2022 Draft Guidelines, CDC/ATSDR has updated and expanded the 2013 Guidelines to provide STLT public health agencies and other interested parties with access to information about current scientific tools and approaches to assess and respond to unusual patterns of cancer in communities. CDC/ATSDR plans to update the evidence base to include final reports associated with several of the inputs gathered to inform the 2022 Draft Guidelines.

CDC/ATSDR developed the 2022 Draft Guidelines using input from a variety of stakeholders including STLT public health agencies, subject matter experts from academia and non-governmental organizations, an internal CDC/ATSDR steering committee, public comments received from a previous announcement in the Federal Register (84 Fed. Reg.

21786, Docket No. CDC-2019-0045), and focus groups conducted with community members and organizations that have been involved with cancer concerns in their communities. CDC/ATSDR also gathered input from a literature review and media scan and evaluated advances in the field of environmental epidemiology (e.g., geospatial methods) and community engagement strategies. An Environmental Media Scan Report, CSTE Workgroup Report (https://cdn.ymaws.com/www.cste.org/resource/resmgr/environmentalhealth/CSTE_Cancer_Cluster_Guidelin.pdf) and STLT Survey and Focus Group Report (<https://www.cdc.gov/nceh/clusters/survey-report.html>) have been developed or are in the process of being developed and will be published on the CDC Cancer Clusters website (<https://www.cdc.gov/nceh/clusters/guidelines.htm>) once available.

As a result of these inputs, key themes emerged:

- 1.) The need for enhanced and improved engagement with communities;
- 2.) The need to deemphasize reliance on statistical significance so that statistical significance is not the deciding factor when evaluating the criteria to address cancer rates and environmental concerns;
- 3.) The need for routine, proactive evaluation of cancer data; and

4.) The need for tools and templates for standardized information collection and data evaluation.

The 2022 Draft Guidelines address each of these themes in the following ways.

- Theme 1: Throughout the 2022 Draft Guidelines, the importance of communication and community engagement are addressed. Additionally, a section and one of the new recommended phases are devoted to communicating with and engaging communities, including identification of a community point of contact. These parts of the guidelines highlight and reinforce the need for establishing clear and ongoing communication channels about activities and challenges associated with the evaluation of unusual patterns of cancer and environmental concerns.
- Theme 2: The four-step approach to evaluate patterns of cancer and identify factors of concern to the community recommended in the 2013 Guidelines has been replaced with ten new criteria to clarify additional efforts that may be required. Statistical significance of the estimates for cancer rates is one among these criteria; however, the 2022 Draft Guidelines recommend that statistical significance alone should not be the deciding factor when evaluating the patterns of cancer. Further assessment and suggested actions are provided to include consideration of health equity and

environmental justice issues when responding to community inquiries.

- Theme 3: The 2022 Draft Guidelines propose an approach for identifying and investigating unusual patterns of cancer as part of routine surveillance activities. The updates introduce a new section encouraging proactive evaluation of cancer registry data on a routine basis to monitor cancer trends and identify unusual patterns. The 2022 Draft Guidelines also suggest that state health officials conduct routine monitoring of cancer data in an area of concern in situations when the criteria do not suggest further action at that time.

- Theme 4: New standardized data collection templates are provided to assist with the uniform collection of information during an inquiry from the community. Data collected and electronically transmitted will also enable CDC/ATSDR to have a clearer understanding of types of cancer and environmental concerns nationally.

Other tools and resources included providing guidance regarding how to evaluate the new criteria. For example, decision trees are included to assist with understanding the new phases, the flow of activities, and reinforcing the proactive approach for routine evaluation of cancer surveillance data. A new tool for evaluating standardized incidence ratios (SIR) is also described. The SIR is a

ratio of the number of observed cancer cases in the study population compared to the number that would be expected if the study population experienced the same cancer rates as a selected reference population (typically the state as a whole is used as a reference population). This tool will be available on the National Environmental Public Health Tracking Network (<https://ephtracking.cdc.gov/>). It will provide SIR estimates by county to enable review of cancer data by the public and STLT partners.

In addition to these updates, other proposed changes in the 2022 Draft Guidelines include the following:

- Changing the name of the guidelines to reflect consideration of environmental concerns as a factor when investigating a community inquiry about unusual patterns of cancer;
- Revising the definition of a cancer cluster;
- Including specific and standardized approaches to better engage community members;
- Explaining how to use a standardized template to better document the nature and extent of cancer and environmental concerns; and
- Enhanced appendices describing statistical and geospatial methods supporting the evaluation of unusual patterns of cancer.

For more information about the process of developing the 2022 Draft Guidelines, please visit <https://www.cdc.gov/nceh/clusters/guidelines.htm>.

Supporting and Related Material in the Docket

The 2022 Draft Guidelines can be found in the Supporting Materials tab of this docket.

Angela K. Oliver,

Executive Secretary,

Centers for Disease Control and Prevention.

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